

Serial No.: Not known

Filing Date: Herewith

Attorney Docket No. 141.016US01

Title: MOULDING PROCESS

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**Amendments to the Claims**

This listing of claims will replace all prior versions and listings of claims in the application:

**Listing of claims**

1. (Currently amended) A method of producing a plurality of soft contact lenses comprising the steps of:

A. providing a sheet of solid, substantially dry material[[]] ;

B. forming said material into a plurality of shaped lens blanks through controlled application of physical force to the material;

C. hydrating said plurality of shaped lens blanks[[]] ;

wherein at least immediately subsequently to said physical forming step B, said plurality of shaped lens blanks remain at least partially attached to the sheet of material.

2. (Original) A method of producing a plurality of soft contact lenses according to claim 1, wherein said sheet of solid substantially dry material is water soluble above a certain temperature, and formed into said plurality of shaped lens blanks at a temperature below said certain temperature.

3. (Original) A method of producing a plurality of soft contact lenses according to claim 2, in which said certain temperature is approximately 50°C.

4. (Original) A method of producing a plurality of soft contact lenses according to claim 2, in which said certain temperature is approximately 65°C.

5. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any of claims 1 to 4~~ claim 1, in which the said material is chosen from the group consisting of

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polyvinyl alcohol or a copolymer of polyvinyl alcohol and polyvinyl acetate or polyethylene-maleic-anhydride or polymethyl-hydroxy-propyl-cellulose or copolymers of methyl acrylate or ethyl acrylate with ethylene or their hydroxyl derivatives.

6. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any preceding claim~~ claim 1, in which said material is a copolymer of polyvinyl alcohol and polyvinyl acetate where the degree of hydrolysis, as measured by saponification, is at least 96% mol based on the original polyvinyl alcohol.

7. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any preceding claim~~ claim 1, in which said material is a substantially uncrosslinked polymer comprising crosslinkable groups and in which, prior to the hydration step C, high energy is applied to said plurality of shaped lens blanks, whereby said polymer is crosslinked to a predetermined, desired crosslink density.

8. (Original) A method of producing a plurality of soft contact lenses according to claim 7 in which the material contains additives that react to the application of high energy to improve crosslinking efficiency.

9. (Currently amended) A method of producing a plurality of soft contact lenses according to claim 7 ~~or 8~~, in which the application of high energy involves irradiation of the plurality of shaped lens blanks by a form of high energy chosen from the group consisting of electron beam irradiation or gamma irradiation or microwave irradiation or ultraviolet irradiation or infrared irradiation or thermal irradiation or ultrasound irradiation.

10. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any preceding claim~~ claim 1, wherein said material is provided in sheet form.

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11. (Original) A method of producing a plurality of soft contact lenses according to claim 10, in which the sheet is used as a transport medium or carrying mechanism for said plurality of shaped lens blanks.

12. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any preceding claim~~ claim 1, wherein said plurality of shaped lens blanks are fully removed from the sheet at a stage after step B by the use of a laser cutting device.

13. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any preceding claim~~ claim 1, in which the physical forming step B is carried out using any one of the group of physical forming processes from the group consisting of thermoforming or vacuum forming or pressing or hot moulding or cold moulding or compression moulding or injection moulding.

14. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any preceding claim~~ claim 1, in which said physical forming step B comprises the following substeps:

B.1 ~~Heating~~ heating said material to a temperature that:

a) is near to the softening temperature of the material, whereby thermoforming of said material is possible, but

b) is below the melting point of said material, whereby the physical integrity of said material is maintained; and

B.2 ~~Thermoforming~~ thermoforming said plurality of shaped lens blanks through application of physical force to said material.

15. (Original) A method of producing a plurality of soft contact lenses according to claim 14, in which said thermoforming sub-step involves compression of the material between two forms or platens.

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16. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any of the preceding claims~~ claim 1, in which the physical forming step B involves the use of moulds and said material is placed between said moulds which are pressed together to form said plurality of shaped lens blanks.

17. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any of the preceding claims~~ claim 1, in which high energy is applied to said plurality of shaped lens blanks and/or to said plurality of soft contact lenses in order to sterilise them.

18. (Currently amended) A method of producing a plurality of soft contact lenses according to claim 17, in which the application of high energy involves irradiation by a form of high energy ~~chosen~~ chosen from the group consisting of electron beam irradiation or gamma irradiation or microwave irradiation or ultraviolet irradiation.

19. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any of the preceding claims~~ claim 1, which comprises the further step of:

D. transferring the plurality of shaped lens blanks to a plurality of final packs.

20. (Original) A method of producing a plurality of soft contact lenses according to claim 19, in which, before the transferring step D, the final packs are sterilised.

21. (Currently amended) A method of producing a plurality of soft contact lenses according to claim ~~19~~ or 20, in which, either before or after the transferring step D, aseptic or sterile solution is added to the sterile final ~~pack~~ packs which solution acts to hydrate the lenses in step C.

22. (Currently amended) A method of producing a plurality of soft contact lenses according to claim 19, in which the material of the shaped lens blanks undergoes a chemical reaction, such as hydrolysis, in the final ~~pack~~ packs.

23. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any preceding claim~~ claim 1, in which all process steps subsequent to step B are carried out without further human contact or handling.

24. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any preceding claim~~ claim 1, which method is automated or semi-automated to run in a continuous or semi-continuous manner.

25. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any of the preceding claims~~ claim 1, which further involves quality control inspections on the shaped lens blanks only.

26. (Currently amended) A method of producing a plurality of soft contact lenses according to ~~any of the preceding claims~~ claim 25, which involves either visual quality control inspections or quality control inspections using an optical system.

27. (Currently amended) A soft contact lens produced according to a method of producing a plurality of soft contact lenses according to ~~any of the preceding claims~~ claim 1.

28. (Currently amended) An apparatus for producing a plurality of soft contact lenses comprising:

[[ - ]] a forming means for applying a controlled physical force to a sheet of material in order to form a plurality of shaped lens blanks;

[[ - ]] sheet material transport means for transporting a sheet of material.

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29. (Original) An apparatus according to claim 28 in which said sheet material transport means comprises driven and/or undriven roller means.

30. (Currently amended) An apparatus according to ~~either of claims 28 or 29~~ claim 28 in which said sheet material transport means comprises gripping means for gripping an edge of the sheet of material and guiding means for guiding said gripping means along a desired trajectory.

31. (Original) An apparatus according to claim 30 in which said guiding means comprises driven and/or undriven chain means and/or belt means.

32. (Currently amended) An apparatus according to ~~any of claims 28 to 31~~ claim 28 in which said forming means comprises a plurality of forms or platens arranged so as to press together to form the sheet of material into a plurality of shaped lens blanks.

33. (Original) An apparatus according to claim 32 in which at least one of said plurality of forms or platens is provided with heating means whereby said sheet of material may be heated in order to facilitate the forming process.

34. (Currently amended) An apparatus according to ~~either of claims 32 or 33~~ claim 32 in which said plurality of platens are removably connectable with a plurality of male and female inserts, which inserts are formed to appropriate shapes to form the shaped lens blanks to desired optical specifications.

35. (Currently amended) An apparatus according to claim 34 in which the inserts are arranged such that either positive or negative pressure ~~(either positive or negative)~~ may be applied through them.

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36. (Currently amended) An apparatus according to ~~any of claims 28 to 35~~ claim 28 which further comprises packaging means for transferring said shaped lens blanks into final packs.

37. (Original) An apparatus according to claim 36 in which said packaging means is arranged to carry out packaging in a substantially sterile environment.

38. (Currently amended) An apparatus according to ~~any of claims 28 to 37~~ claim 28, which further comprises removing means for removing said shaped lens blanks from the sheet of material and for forming the circumferential edges of the shaped lens blanks.

39. (Original) An apparatus according to claim 38 in which said removing means is a laser cutting means.

40. (Original) An apparatus according to claim 39 in which said laser cutting means comprises a CO<sub>2</sub> laser.

41. (Currently amended) An apparatus according to ~~any of claims 29 to 40~~ claim 28, which further comprises high energy application means for applying high energy to said shaped lens blanks and/or to soft contact lenses formed from said shaped lens blanks.

42. (Original) An apparatus according to claim 41 in which said high energy application means comprises an electron beam irradiation means.

43. (Currently amended) A soft contact lens produced by an apparatus according to ~~any of claims 28 to 42~~ claim 28.